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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/269,860 03/10/00 ANKENBAUER

W 4453

EXAMINER

HM22/0605

DOUGLAS A PETRY  
ROCHE MOLECULAR SYSTEMS  
1145 ATLANTIC AVENUE  
ALAMEDA CA 94501

HUTSON, R

ART UNIT

PAPER NUMBER

1652

DATE MAILED:

06/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
**09/269,860**

Applicant(s)

**Ankenbauer et al.**

Examiner

**Richard Hutson**

Art Unit

**1652**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-7, 11-13, 15, 16, and 23-25 is/are pending in the application.
- 4a) Of the above, claim(s) 11-13, 15, 16, and 23-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, and 5-7 is/are rejected.
- 7) ☒ Claim(s) 3 is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirements.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 12
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

Art Unit: 1652

### DETAILED ACTION

Claims 1-3, 5-7, 11-13, 15, 16 and 23-25 are still at issue and are present for examination.

Applicant's election of Group I, Claims 1-3 and 5-7 without traverse in Paper No. 11 is acknowledged. Claims 11-13, 15, 16, 23-25 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

1. Claims 1 and 7 are objected to because of the following informalities: Claim 1 recites “...*Pyrococcus furiosus*” This name is incorrectly spelled and should be *Pyrococcus furiosus*. Appropriate correction is required.

#### *Specification*

2. The use of the trademark Thesit has been noted in this application. It should be capitalized wherever it appears and **be accompanied by the generic terminology**.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

#### *Claim Objections*

3. Claims 3 and 7 are objected to because of the following informalities: Claim 7 recites the trademark “Thesit”. It is suggested that this be replaced by the appropriate “**generic terminology**”.

Claim 3 is objected to because it depends from rejected claim 1.

Appropriate correction is required.

Art Unit: 1652

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 2, and 5-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

6. Claims 1, 2, 5, 6 and 7 are directed to all possible purified DNA polymerases from *Thermococcus gorgonarius* which catalyze the template directed polymerization of DNA, possesses 5'-3' polymerase activity and is characterized by at least two-fold greater replication fidelity than DNA polymerase obtainable from *Pyrococcus furiosus* (claim 1), wherein said DNA polymerase retains about 90% of its activity after incubation for two hours at about 95°C in the presence of a stabilizer (claim 2), and a composition comprising said polymerase and a stabilizer (claim 5), wherein said stabilizer is a non-ionic detergent (claim 6) such as Thesit and/or Nonident P40 (claim 7). It is well known in the art that most organisms comprises multiple structurally diverse DNA polymerase species. The claimed genus is a large variable genus with potentiality of comprising many different DNA polymerases some of which have not yet been identified. The specification, however, only provides a single representative species of the

Art Unit: 1652

claimed genus of DNA polymerases from *Thermococcus gorgonarius*, specifically that DNA polymerase having the amino acid sequence of SEQ ID NO: 7. There is no disclosure of any particular structure to function/activity relationship in the single disclosed species. The specification also fails to describe additional representative species of these DNA polymerases by any identifying structural characteristics or properties other than the activities recited in claims 1, 2, 5, 6 and 7, for which no predictability of structure is apparent. Given this lack of additional representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at [www.uspto.gov](http://www.uspto.gov).

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on M-F from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapy Achutamurthy (Murthy), can be reached on (703) 308-3804. The fax number for Official Papers to Technology Center 1600 is (703) 305-3014.

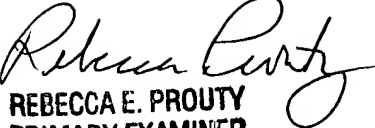
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Application/Control Number: 09269860

Page 5

Art Unit: 1652

Richard Hutson Ph.D.  
5/23/2001

  
REBECCA E. PROUTY  
PRIMARY EXAMINER  
GROUP 1800  
1652